FORM HR-RM 1
(11-1-66)
Hall of Records Commission

REQUEST FOR RECORDS RETENTION SCHEDULE

To be Submitted to the Records Management Division
Hall of Records Commission

1914
116

SCHEDULE NO. 456

PAGE NO. 1

1. Requesting Agency
~~Institute of International Medicine~~ DEPT. OF SOCIAL AND PREVENTIVE MEDICINE

2. Division or Bureau of Requesting Agency
~~Division of Epidemiology & Biostatistics~~ CLINICAL INVESTIGATION

3. Authorization Requested (Check only one of the squares below).

A [ ] Dispose of present accumulation. No additional accumulation is anticipated. Records have ceased to have value to warrant retention.

B [ ] Establish retention schedule for records for which there is a continuing accumulation. The records will cease to have value to warrant their retention after the period of time indicated.

C [X] Microfilm and destroy originals. Originals if not microfilmed would be retained for the period of time indicated.

4. Item No.	5. Description of Records Describe records accurately. Include title, form number, size of documents, work or activity to which the records relate, inclusive dates, and quantity (cubic or linear feet). Show recommended retention period.	6. Recommendation of Hall of Records and Board of Public Works.

The Division of Epidemiology and Biostatistics, under the auspices of the ~~Institute~~ DEPARTMENT OF SOCIAL AND PREVENTIVE MEDICINE of ~~International Medicine~~ the School of ~~Medicine~~ with the University of Maryland, acts as Coordinating Center for two studies supported by the National Institutes of Health. One study in which the Division is presently engaged is concerned with vascular complications in diabetes; a cooperative study of twelve clinics in operation since (SEPT. 1960) which is supported by grants from the NIAMD. The Division is also currently acting as Coordinating Center for the cooperative study of drugs and coronary heart disease which is supported by the National Heart Institute and which has a participation of approximately 55 clinics since its inception (April) in 1965.

The Coordinating Center acts as recipient of all information pertinent to these studies from the various clinical centers and from the laboratories involved. This information is edited at specific intervals by computer and the Coordinating Center notifies the various clinics of any outstanding form omissions and of data which is considered questionable, either because it is outside the range of normal values or because there is an unreasonable change observed since the last examination of these patients. At intervals,

7. Agency, Division or Bureau Representative

CHRISTIAN R. KLIMT, M.D., DR.P.H. — Signature
PROFESSOR AND DIRECTOR — Title
MAY 17, 1968 — Date

Schedule Authorized as Indicated in Col. 6 by Hall of Records Commission.

JUN 13 1968 — Date
Morris S. Radoff — Archivist

Disposal Authorized as Indicated in Col. 6 by Board of Public Works.

6-24-68 — Date
Secretary

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the Coordinating Center also makes basic analyses in order to determine specific results to accomplish the above. All data concerning the patients cooperating in these studies are forwarded to the Coordinating Center in original form and stored in the center until needed for the analyses. Over a period of five years, approximately two million, two hundred and fifty thousand sheets will have been collected for analysis and due to the limited space within the center for storage, it has become essential for us to microfilm data collected.

Forms to be microfilmed are as follows:

1. CORONARY DRUG PROJECT

   a) CDP Form 01 Title: Admission Form
   Approximate Number of Pages: Nine

   b) CDP Form 02 Title: Initial Visit Three Baseline Form
   Approximate Number of Pages: Five

   c) CDP Form 03 Title: Treatment Adjustment Form
   Approximate Number of Pages: Five

   d) CDP Form 04 Title: Non-Annual Follow-Up Examination Form
   Approximate Number of Pages: Seven

   e) CDP Form 05 Title: Annual Follow-Up Examination Form
   Approximate Number of Pages: Ten

2. UNIVERSITY GROUP DIABETES PROGRAM

   a) UGDP Form 06 Title: Initial Examination And Trial Observation Period
   Approximate Number of Pages: Seven

   b) UGDP Form 09 Title: Quarterly Follow-Up Examination
   Approximate Number of Pages: Five

   c) UGDP Form 12 Title: Annual Eye Examination
   Approximate Number of Pages: Three

   d) UGDP Form 13 Title: Annual Heart Examination
   Approximate Number of Pages: Two

   e) UGDP Form 14 Title: Annual Kidney Examination
   Approximate Number of Pages: Two

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f) UGDP Form 15 Title: Peripheral Vascular Examination
Approximate Number of Pages: Four

RECOMMENDATION:

Retain Original of Forms Minimum of Six Months and Then Upon Microfilming and Verifying Said Microfilm, Destroy Original Copy.

Preparation of the Forms for Microfilming:

Forms will be held at least six months from the date of processing by the Coordinating Center in preparation for microfilming. The forms in the CDP and in the UGDP that are to be microfilmed will be computer edited a second time at least two weeks prior to any microfilming. All form questions must be complete and must pass the edit before microfilming occurs.

The forms to be microfilmed will be prepared in the following manner.

I. CDP FORMS

1. Baseline Forms (01, 02, and 03):

a) Two preface pages precede each baseline form to be microfilmed. These preface sheets, when filmed, can be seen visually without using a viewer. This increases the efficiency in correcting and stuffing the microfilm in the jackets. Also, the preface pages are used as an index system in the permanent storage and filing of the microfilm using the patient identification and form number system. The pages are 8½ x 11 inches and are coded by using black marking pencil. The first page indicates the patient identification number. The second page uses the code "0" to code a baseline examination. The form number is indicated directly below the baseline code. Upon completion of the preface pages, staples are removed from the form and each page of the form is checked for the correct patient identification number. The form is then placed behind the preface pages.

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b) After this is accomplished, a final 8½ x 11 inch sheet coded with an "X" is inserted to designate to the jacket filler to cut microfilm and to start the filling of another jacket. Currently, Forms 01 and 02 are placed into one jacket; each form on a separate line. Form 03 is currently inserted in a separate jacket. The Form 03 uses the same procedure described above.

2. Follow-Up Visit Forms (04 and 05):

a) Two preface pages precede each follow-up visit form to be microfilmed. These pages are 8½ x 11 inches and are coded by using black marking pencil. The first page indicates the patient identification number. The second page indicates the specific follow-up visit number; the form number is indicated directly below the follow-up visit number. Upon completion of the preface pages, the staple is removed from the form and each page of the form will be checked for the correct patient identification number. The form is then placed behind the preface pages.

b) After this is completed, the final 8½ x 11 inch sheet coded with an "X" is inserted to designate to the jacket filler to cut microfilm and to start filling another jacket.

II. UGDP FORMS

1. Baseline Forms (06, 12, 13, and 14):

a) Two preface pages precede each baseline form to be microfilmed with the exception of Form 15. The pages are 8½ x 11 inches and are coded by using black marking pencil. The first page indicates the patient identification number. The second page uses the code "0" to indicate a baseline examination; The form number is indicated directly below the baseline code. Upon completion of the preface pages, staples are removed from the form and each page of the form

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is checked for the correct patient identification number. This procedure is used for Forms 06, 12, 13, and 14. Form 15 will follow the same procedure as above with the exception of the preface pages. Form 15 will have one preface page indicating only the baseline code with the form number indicated directly below same.

b) A final insert page marked "X" will follow the accumulated baseline forms for each patient. This indicates to the jacket filler to cut microfilm and to start the filling of another jacket. Currently, baseline forms are being accumulated for one year for each patient and placed into one jacket with each form on a separate line. This occurs with all the baseline forms with the exception of Forms 14 and 15. These forms are put in one line of the jacket. As stated above, Form 14 will have two preface sheets, Form 15 will have one. The preface sheet will indicate to the stuffer that the form is to continue on the same line as the previous form.

2. UGDP Follow-Up Visit Forms (09, 12, 13, 14, and 15):

a) Each follow-up visit will contain two forms. There will always be a Form 09 followed by either a Form 12, 13, 14, or 15. Preceding the follow-up Form 09 are two preface pages. These pages are 8½ x 11 inches and are coded by using black marking pencil. The first page indicates the patient identification number. The second page indicates the specific follow-up visit number; the form is indicated directly below the follow-up visit number. Immediately following Form 09 will be the second follow-up visit form. However, preceding the second form, only one preface sheet is inserted. This preface page indicates the specific follow-up visit number and the form number is indicated directly below the visit number. Upon completion of the preparation of the

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second form, the staples will be removed from both forms and each page of each form is checked for the correct patient identification number.

b) After this is completed, the final 8½ x 11 inch sheet coded with an "X" is inserted to designate to the jacket filler to cut microfilm and start filling another jacket. Each patient follow-up visit will be stored in a separate jacket. Eventually, these follow-up visits may be put together in one jacket for one patient year.

The processing procedure described for the CDP and UGDP baseline forms and the follow-up visit forms is also used to microfilm missing forms due to missed patient visits. Pages coded with an "M" are inserted behind the preface sheets. "M" is the code used for missing forms. There will be an "M" for each page missing. (i.e., CDP Form 01 has nine pages, therefore, nine "M"s would be used).

All corrections on previously microfilmed forms are to be re-microfilmed in the following manner: A separate file will contain all microfilm corrections and will be microfilmed separately from the forms being microfilmed for the first time. Only the corrected pages are to be re-microfilmed and then inserted into the proper jacket at the end of the original microfilmed form. To indicate a correction on the microfilm, an adhesive dot will cover the original page. This will indicate that a correction has been made and to go to the end of the line to see the corrected page. NJP

Conditions and Specifications for Microfilming:

General conditions and specifications for microfilming forms of the CDP and the UGDP are as follows: microfilming is done on the premises (Howard Hall, 660 West Redwood Street, Baltimore, Maryland 21201) with labor, material, and equipment provided by the successful vendor in bidding. Images are inserted in jackets by automatic filling process. When chamber of jacket is not completely filled, the images are moved to the left hand margin so they may be read in an orderly fashion showing first the patient identification number

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and then the form identification number. The documents to be microfilmed are 8½ x 11 inch printed sheets or xeroxed sheets on 20 weight paper. Approximately 200,000 images are to be microfilmed semi-annually. The diameter reduction to be used is 24 to 1. The pages are to be in form number sequence by patient identification and by form. The automatic feeding process is to be used in filming these images. The camera to be used is solely according to the vendor's recommendation as long as requirements are within the specifications requested. The microfilm to be used must have antihilation under-coating to assure optimum quality. All microfilming is produced in the manner prescribed by the National Bureau of Standards for the production of permanent microfilm copy. The vendor must have the capacity and ability to use AHU film. The forms are filmed on rolls and then put in microthin jackets, three and three eighths inches by seven and three eighths inches. Jackets are manufactured to the following specifications: .003 polyester stable + 1 - .0002; ribbing of paper is .0006 thick + 1 - .0002; overall jacket thickness is approximately .011 inches + 1 - .005. The jacket is the same size as that of a computer punched card. This size is basically being used to facilitate storing the microfilm in our rotating file with the punch cards used in data processing. Jackets will be notched uniformly by clinic number to give visual aid in files. A diazo copy is made for each filmed roll. Designated targets and other necessary identification is used to conform with Federal and State laws for microfilming. Upon completion of the microfilming, the vendor must inspect all microfilm images frame by frame on a microfilm reader to guarantee complete readability of the microfilm reproduction. Lite box inspection only, is not permitted. In the event that any document is not legible on the microfilm, the entire case must be rephotographed.

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Approximate Cost Every Six Months:

1.	Microfilming Images	(200 M)	$1,850.00
2.	Microfilm Jackets	(18 M)	1,365.30
3.	Automatic filling of Jackets	(18 M)	540.00
4.	Hand processing images to left hand margin when images do not fill a chamber and for notching jackets		262.50
		TOTAL	$4,017.80

Inspection of Microfilmed Images:

When the forms have been microfilmed on the premises by the successful bidding vendor, they will then be stored until the microfilming performed has been adequately inspected by this Division. Upon the completion of the microfilming and inspection performed by the vendor as stated in the microfilm specifications, the original microfilm and diazo copy is returned to the Coordinating Center for our verification. Inspection of microfilming is accomplished by the Coordinating Center in the following manner:

1. The jackets are returned in order by clinic, patient, and form. Each jacket is checked to verify that no form has been missed in microfilming. This is accomplished in the CDP and the UGDP by checking each jacket against an inventory listing of the forms received by the Coordinating Center from the various clinics. In checking each jacket against the inventory, every 25th jacket is pulled and the microfilm therein is viewed in the microfilm viewer for clarity, accuracy and proper insertion of form images as indicated by preface sheets.
2. Any errors found in the microfilming are then returned to the vendor. The appropriate forms are then re-microfilmed in toto according to the microfilm specifications stated

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previously.

As of this date, we have only microfilmed one time. The experience with regard to this microfilming shows that upon following the outline preparation procedures by both our office and the vendor, errors are small relative to the number of pages microfilmed.

Filing of Microfilm Records:

The microfilm records for the CDP and UGDP are filed in a permanent file according to clinic number, by patient, and form. Each patient has an index card which can be easily seen at a glance upon looking at a number of microfilmed records. These are 7 3/8" x 3 1/4" acetate self indexes manufactured by Acme Visible Records, Inc. The indexes were cut to meet the specifications of the Coordinating Center so as to be able to view the index numbers readily. Also, this was done so as to view the clinic number identification punched on the jacket. To increase the efficiency in making patient identification numbers that would fit in the acetate, it was resolved that rather than typing these numbers on some sort of card that the computer could be utilized in reproducing the patient identification numbers. The computer gave us a print out of all patients currently in the study and further gave us a print out of cards of anticipated patient identification numbers to be entered into the study. These tab cards were then forwarded to Acme Visible and cut to fit the acetate self indexes. The Coordinating Center is anticipating approximately ten thousand patients in the CDP study and the UGDP has a participation of patients in the number of 1,027. The cost for indexing these patients as described above is in the amount of $654.75. If indexing had been directly done on the jacket as originally anticipated, it would have cost approximately $2000.00. This is a savings of over $1,300 by using the acetate index system.

A duplicate of all microfilming is stored in a vault at the Main Office - Maryland National Bank, Baltimore, Maryland. This precaution is taken in the event all records located at 660 West

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Street are destroyed in some manner, the UGDP and the CDP studies may continue to be operational.

Upon filing the microfilm, both original and the duplicate, all original forms photographed are to be destroyed at the earliest convenient time.